WHAT IS CLAIMED IS:

1. A process of preparing orlistat, comprising the steps of hydrogenating lipstatin in an organic solvent in the presence of a catalyst to obtain orlistat.

2. The process of claim 1, wherein the organic solvent is selected from the group consisting of acetonitrile, alcohol, and acetone.

3. The process of claim 2, wherein the alcohol is methanol.

4. The process of claim 1, wherein the catalyst is selected from the group consisting of palladium and nickel.

5. The process of claim 1, wherein the hydrogenating step is performed at a temperature between about 10^0C to about 50^0C.

6. The process of claim 1, wherein the hydrogenating step is performed at pressure of less than 5 bar.

7. The process of claim 1, wherein the hydrogenating step is performed at pressure between about 1 to about 3 bar.

8. The process of claim 1, wherein the hydrogenating step is performed at pressure of about 1 bar.

9. A crystalline solid orlistat, or hydrate or solvate thereof, characterized by data selected from the group consisting of a XRD pattern with peaks at 5.8, 18.5, 19.5 and 22.3 ± 0.2 degrees two-theta and a DSC melting endotherm at about 46.7^0C.

10 The crystalline solid orlistat of claim 9, wherein the crystalline solid orlistat is characterized by the XRD pattern with peaks at 5.8, 18.5, 19.5 and 22.3 ± 0.2 degrees two-theta.

11. The crystalline solid orlistat of claim 10, wherein the crystalline solid orlistat is further characterized by a XRD pattern substantially as depicted in Figure 1.

12. The crystalline solid orlistat of claim 9, wherein the crystalline solid orlistat is characterized by the DSC melting endotherm at about 46.7^0C.

13. A crystalline solid orlistat, or hydrate or solvate thereof, characterized by data selected from the group consisting of a XRD pattern with peaks at 4.8, 5.6, 14.9, 17.3, 19.2 and 22.0 ± 0.2 degrees two-theta, and a DSC melting endotherm at about 46.6^0C.

14. The crystalline solid orlistat of claim 13, wherein the crystalline solid orlistat is characterized by the XRD pattern with peaks at 4.8, 5.6, 14.9, 17.3, 19.2 and 22.0 ± 0.2 degrees two-theta.

15. The crystalline solid orlistat of claim 14, wherein the crystalline solid orlistat is further characterized by a XRD pattern substantially as depicted in Figure 2.

16. The crystalline solid orlistat of claim 13, wherein the crystalline solid orlistat is characterized by a DSC melting endotherm at about 46.6°C.

17. A process of preparing crystalline solid orlistat, or hydrate or solvate thereof, characterized by data selected from the group consisting of a XRD pattern with peaks at 5.8, 18.5, 19.5 and 22.3 ± 0.2 degrees two-theta and a DSC melting endotherm at about 46.7°C, comprising the steps of:

(a) dissolving orlistat in a solvent;
(b) adding an anti-solvent or water to the solvent; and
(c) isolating the crystalline solid orlistat.

18. The process of claim 17, wherein the solvent is a lower alkyl alcohol, acetone, acetonitrile, acetone, ethyl acetate, isobutyl acetate, methyl isobutyl ketone, and hexane.

19. The process of claim 18, wherein the lower alkyl alcohol is selected from the group consisting of methanol, ethanol, n-propanol, and isopropanol.

20. The process of claim 17, wherein the anti-solvent is a hydrocarbon.

21. The process of claim 20, wherein the hydrocarbon is selected from the group consisting of hexane, cyclohexane and heptane.

22. The process of claim 17, wherein the solvent is methanol and the anti-solvent is hexane.

23. The process of claim 17, wherein the steps (a) to (c) are repeated at least once to increase the purity of the crystalline solid orlistat.

24. The crystalline solid orlistat prepared in accordance with the process of claim 17.

25. The crystalline solid orlistat of claim 24, wherein the crystalline solid orlistat is characterized by a XRD pattern with peaks at 5.8, 18.5, 19.5 and 22.3 ± 0.2 degrees two-theta.

26. The crystalline solid orlistat of claim 25, wherein the crystalline solid orlistat is further characterized by a XRD pattern substantially as depicted in Figure 1.

27. The crystalline solid orlistat of claim 24, wherein the crystalline solid orlistat is characterized by a DSC melting endotherm at about 46.7°C.

28. A process for preparing a crystalline solid orlistat, or hydrate or solvate thereof, characterized by data selected from the group consisting of a XRD pattern with peaks at 4.8, 5.6, 14.9, 17.3, 19.2 and 22.0 ± 0.2 degrees two-theta, and a DSC melting endotherm at about 46.6°C, comprising the steps of:

(a) mixing orlistat in hexane to form a mixture at a first temperature;

(b) lowering the first temperature of the mixture sufficiently to precipitate; and

(c) isolating crystalline solid orlistat.

29. The process of claim 28, wherein the steps (a) to (c) are repeated at least once to increase the purity of the crystalline solid orlistat.

30. The crystalline solid orlistat prepared in accordance with the process of claim 28.

31. The crystalline solid orlistat of claim 30, wherein the crystalline solid orlistat is characterized by the XRD pattern with peaks at 4.8, 5.6, 14.9, 17.3, 19.2 and 22.0 ± 0.2 degrees two-theta.

32. The crystalline solid orlistat of claim 31, wherein the crystalline solid orlistat is further characterized by a XRD pattern substantially as depicted in Figure 2.

33. The crystalline solid orlistat of claim 30, wherein the crystalline solid orlistat is characterized by the DSC melting endotherm at about 46.6°C.

34. A process of preparing a mixture of crystalline solid orlistat, or hydrate or solvate thereof, characterized by data selected from the group consisting of a XRD pattern with peaks at 5.8, 18.5, 19.5 and 22.3 ± 0.2 degrees two-theta, a DSC melting endotherm at about 46.7°C, a XRD pattern with peaks at 4.8, 5.6, 14.9, 17.3, 19.2 and 22.0 ± 0.2 degrees two-theta, and a DSC melting endotherm at about 46.6°C, comprising the steps of:

(a) dissolving orlistat in a solvent; and

(b) inducing crystallization to obtain the mixture of crystalline solid orlistat.

35. The process of claim 34, wherein the solvent is at least one alcohol selected from the group consisting of methanol, ethanol, n-propanol, 1-propanol, 2-propanol, isopropanol, 1-butanol, i-butanol, sec-butanol, tert-butanol, N,N-dimethyl formamide, dimethyl sulfoxide, acetonitrile, acetone, ethyl acetate, isobutyl acetate, methyl isobutyl ketone, and acetic acid.

36. The process of claim 34, wherein solvent is an aliphatic hydrocarbon.

37. The process of claim 36, wherein the aliphatic hydrocarbon is selected from the group consisting of hexane, pentane and heptane.

38. The process of claim 34, wherein the solvent contains water.

39. The process of claim 34, wherein the solvent is methanol.

40. The process of claim 34, wherein the mixture of methanol and water is present in a v/v ratio of about 1:0.3.

41. The process of claim 35, wherein the solvent is a mixture of a first alcohol in combination with a second alcohol selected from the group consisting of methanol, ethanol, isopropanol, propanol, butanol, sec-butanol and t-butanol.

42. The process of claim 34, wherein the crystallization step is induced by adding an anti-solvent.

43. The process of claim 34, wherein the crystallization step is induced by cooling.

44. The crystalline solid orlistat as prepared by the process of one of claims 17, 28, and 34, wherein the crystalline solid orlistat has a purity of at least about 95%.

45. The crystalline solid orlistat as prepared by the process of one of claims 17, 28 and 34, wherein the crystalline solid orlistat has a purity of at least about 98%.

46. A process of preparing orlistat, comprising the steps of:

a) preparing fermentation broth containing lipstatin;
b) extracting lipstatin from the fermentation broth;
c) hydrogenating the lipstatin to obtain orlistat; and
d) separating the orlistat.

47. The process of claim 46, wherein the hydrogenating step a) is carried out in an organic solvent in the presence of a catalyst to obtain orlistat.